



# Cancer Trials New Zealand

## CTNZ Annual Scientific Meeting

**Date:** Thursday 30<sup>th</sup> July 2009  
**Venue:** Orams Lounge, Westhaven, Auckland

0900 – 0930 Tea/Coffee and registration

**Session 1**     **0950 – 1050**

0930 – 0950 CTNZ: welcome and update (Michael F/Stephanie Pollard)

0950 – 1050     ***Current Studies***

- Progress reports for recruiting studies: SOLD, SIRFLOX, Selenium (Stephanie Pollard)
- Update on brain tumour registry (David Hamilton)
- HI 5 results and where to next (Bruce Baguley)
- XEN results and where to next (Michael Findlay)

1050 – 1110 *Tea/Coffee Break*

**Session 2**     **1110 – 1215**

***New/Recent Projects***

- XEN substudy : comparing RECIST to CHOI criteria for tumour assessment ( Rekha Raju)
- ASA404 hepatic impairment trial (Michael Findlay)
- Recharge (a medical food) Trial (Geoff Krissansen, Janie Proctor)
- LongCyp: CYP2C19 pharmacogenetics in cancer, the effect of disease progression (Wing Yee)
- SOLD cardiac sub study (Dean Harris)

1215 – 1310 *Lunch*

**1310 – 1330**     ***New projects (continued)***

- The RAZOR Trial (Sanjeev Deva, Vicki Hinder)

**Session 3**     **1330 – 1430**

***Tissue Banking within NZ***

- Tissue Banks around NZ (representation from Christchurch and Middlemore banks)
- Biogrid (Michael Eccles)
- Discussion

**Session 4**     **1430 – 1530**

***Open Session – New Concepts***

- Vaccine +DTIC+ interferon alpha for melanoma (Rod Dunbar)
- Bioinformatics (Cris Print)
- A proposal to collect pre-treatment blood and tissue and drug response data in patients with advanced CRC (John McCall)
- Exploring the use of Imides for the treatment of glioma (Lai-Ming Ching)
- Cyclox III (Dean Harris)

1540 – 1550     ***Summary and Conclusion***



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### Report

**Date of Meeting:** Thursday 30<sup>th</sup> July 2009

#### **Introduction**

The meeting was well attended. Thirty six attendees were present on the day. The audience were truly multidisciplinary and included oncology, nursing, pharmacy, surgical and trial coordination staff from the NZ cancer centre as well as scientists, biostatisticians and other University staff. There are relatively few forums where these groups all come together and it is always a pleasure to see the interactions between these diverse groups with the resultant lively discussion throughout the day! The programme built on last year's successful programme and the sessions followed the various stages of CTNZ trials from those that have completed and presented results to those early concepts and new ideas. In addition a session on the relevant and topical area of tissue banking was included and it was great to have this topic discussed in this arena.

#### **Current Studies**

Stephanie Pollard gave progress reports for the current recruiting studies SIRFLOX, SOLD, the GBM study and the NSCLC and Head & Neck Selenium studies. CTNZ has varying involvement in these studies ranging from national trial coordination and monitoring (SOLD) to provision of statistical and clinical advice (GBM). All 5 studies were recruiting well.

Dr David Hamilton updated the status of the New Zealand National CNS Database which is currently in its first draft and awaiting further refinement of data collection fields. It is anticipated that the database can be piloted at one site in the near future.

The Hi5 study was presented by Professor Bruce Baguley. The study conclusions raised many more questions than answers and the possible role of ascorbate was also discussed.

The final results of the XEN study were presented by Professor Michael Findlay. Results of this study were promising with future developments possible.

#### **New/Recent Projects**

A number of new or recent CTNZ projects were presented this year; the fact that the majority of the trials were borne from local collaborations and involved emerging researchers was a real highlight.

Three new trials that have opened for recruitment so far this year are the ASA404 Hepatic Impairment Trial, Long Cyp and ReCharge. Both Long Cyp and Recharge have come out of collaborations between The University of Auckland, clinicians and CTNZ. Long Cyp was presented by Auckland PhD student Wing Yee. This study builds on the previous work looking at the effect of advanced cancer on the activity of the Cyp2C19 liver enzyme, and will look at whether compromised Cyp2C19 activity occurs at cancer diagnosis and if there are any changes as disease progresses. The study opened for recruitment in July 2009 and aims to recruit 50 patients over a 2 year period.

Dr Geoff Krissansen from The University of Auckland gave an overview of the animal data that lead to the development of the ReCharge™ formulation. Janie Proctor, the Trial Manager, then went over the ReCharge Study, which is a randomised phase IIb, placebo controlled trial to assess the efficacy of ReCharge™ in preventing chemotherapy induced diarrhoea when administered daily to patients undergoing

chemotherapy. This LactoPharma funded trial will compare ReCharge™, an ice cream formulation containing two milk bioactive compounds, to a placebo soy oil ice cream. The study is being lead by Dr David Perez at Dunedin Hospital, with Auckland, Palmerston North and Christchurch Hospitals as participating centres. All sites will open for recruitment in August 2009 and will competitively recruit 200 patients over 9 months.

Dr Michael Findlay presented the ASA404 Hepatic Impairment Trial; much of the early development of this trial was carried out by CTNZ before being picked-up and run in by Novartis. This is a Phase 1 dose escalation study to characterize safety, tolerability and pharmacokinetics of ASA404 in patients with advanced solid tumours and impaired hepatic function. CTNZ is the lead site and opened in July 2009, with Waikato, Wellington and Christchurch sites to follow. Thirty nine patients are required nationally, the first having been recruited last month.

Three further studies that will be opening in the next 6 months were also discussed. The Razor Trial developed by Dr Reuben Broom at Auckland Hospital was presented Dr Sanjeeva Deva and Vicki Hinder. Razor is a phase II trial that will evaluate the addition of Zoledronic acid to RAD001 in patients with advanced renal cell carcinoma and bone metastases in the first-line setting. There was real interest shown in this trial due the poor prognosis among this patient population. The protocol is in the final stages of development, it is expected that ethics approval will be obtained by the end of this year and the trial will be ready to open early next year.

Christchurch's Dr Dean Harris gave an overview of the SOLD Cardiac Sub-Study developed by New Zealand cardiologists and oncologists. The study will involve collection of biomarkers and sophisticated ECHOs. This sub study has been developed in conjunction with a national programme to assess early predictors of heart failure among trastuzumab patients, thus providing the ideal opportunity to assess trastuzumab and cardiac function. Funding is currently being sought for this sub-study.

The Xen Sub-Study has been developed by radiology registrar Dr Rekha Raju. This is a retrospective audit of tumour response according to RECIST and CHOI criteria to assess whether there is any difference in results when assessing tumour in regards to response and progression-free survival. The CHOI criteria takes into account both tumour size and density, whereas RECIST only accounts for tumour size. The ethics application is underway, with a proposed start date of late 2009.

### **Tissue Banking within NZ**

The first topic of the afternoon sessions was tissue banking within New Zealand. Mark Jeffery presented on behalf of the Cancer Society Tissue Bank, Christchurch. He began the session by outlining the history, technical and ethical processes, and current status of the Christchurch Tissue bank, which has been very successful with samples now banked from over 4000 consenting donors, and an average of 500 donors per year. Daphne Mason, curator of the new Middlemore tissue bank established in July 2009, then presented to us the structure, goals and future plans for this new facility. A request was made to the research community for feedback regarding what researchers want out of a tissue bank. The concept of data networking through a platform such as Australia BioGRID was introduced by Mike Eccles of the Pathology Department at the University of Otago. This resource allows linkage of sets of data from multiple institutions and databases via the internet that can be searched and queried seamlessly with authorisation from the data custodians and BioGRID management committee. Discussion that followed the session saw general agreement from the meeting attendees on the necessity and utility of tissue banks in the New Zealand research and clinical environments.

## **Open Session – New Concepts**

Five new concepts were put forward for this open session with an equal mix of clinical and scientific representation.

John McCall presented his proposal to collect tissue, blood and clinical data in order to predict treatment response in patients with colorectal cancer. This proposal was very relevant in light of the prior session on tissue banking and John's point that the collection of specimens and clinical data has to occur in anticipation rather than in response to need was well made. John continues to seek opinions on the usefulness of such a proposal as well as potential funding avenues and the interactions with the tissue banks.

Rod Dunbar presented his current melanoma vaccine concept which he helpfully entitled version 2 as an evolving concept after his presentation at CTNZ meeting last year and the subsequent results and progress from the Ludwig phase II trial. Rod's new concept is to address the question 'Can we boost the immunogenicity by changing the peptide schedule?' He eloquently outlined the reasons why such a protocol would be feasible in the NZ setting and how the partnership between clinical and scientific colleagues would enable better definition of the patient population required and would help ensure logistics and limited funding requirements are achieved.

Lai- Ming Ching presented her ongoing interest in exploring the use of Imides for the treatment of glioma. A significant amount of explorations are ongoing or planned in mice models but Lai-Ming also wishes to explore the possibility of using cyclophosphamide / thalidomide or lenalidomide combinations in humans with multiple myeloma or possibly other solid tumours.

Dean Harris discussed the results from the previous CTNZ Cyclox II trial (A randomized phase II study comparing capecitabine with capecitabine plus oral cyclophosphamide) and then provided a proposal which could be the successor Cyclox trial using metronomic chemotherapy utilizing low dose continuous dosing well below the maximum tolerated dose.

Unfortunately Cris Print was unwell and therefore unable to present his planned update on bioinformatics.

## **Summary and Conclusions**

If you require copies of any of the presentations from the meeting please email [cancertrialsnz@auckland.ac.nz](mailto:cancertrialsnz@auckland.ac.nz) with your request. Please note not all slides will be available for issues of confidentiality and commercial sensitivity.

We look forward to the 2010 annual meeting!



## CTNZ Annual Meeting 2009 Attendees

Title	Name	Role	Organisation
Professor	Bruce Baguley	Co-director	Auckland Cancer Society Research Centre
Ms	Maria Bituin	Clinical Trial Coordinator	Auckland City Hospital Oncology Services
Ms	Gwyn Capes	Research Nurse	Auckland City Hospital Oncology Services
Assoc. Prof.	Lai-Ming Ching	Associate Professor	Auckland Cancer Society Research Centre
Dr	Sanjeev Deva	Registrar	Auckland City Hospital Oncology Services
Ms	Janfrey Doak	NZ Project Officer	Trans Tasman Radiation Oncology Group
Mr	Steve Duffy	Pharmacist	Auckland City Hospital Pharmacy
Dr	Rod Dunbar	Associate Professor	Biological Sciences, University of Auckland
Ms	Marina Dzehali	Charge Nurse Manager	Clinical Research Unit, Wellington Hospital
Professor	Michael Eccles	Professor	Developmental Genetics and Pathology Group, University of Otago
Ms	Belinda Egan	Clinical Trial Coordinator	Christchurch Hospital
Professor	Michael Findlay	Director	Cancer Trials New Zealand
Ms	Anne Fraser	Research Nurse	Auckland City Hospital Oncology Services
Dr	David Hamilton	Radiation Oncologist	Wellington Hospital
Dr	Dean Harris	Medical Oncologist	Christchurch Hospital
Dr	Samar Issa	Haematologist & Tissue Bank Director	Middlemore Hospital
Ms	Vicki Hinder	Biostatistician	Cancer Trials New Zealand
Dr	Christopher Jackson	Medical Oncologist	Dunedin Hospital
Dr	Mark Jeffery	Medical Oncologist	Christchurch Hospital
Ms	Margaret Joppa	Clinical Trial Coordinator	Auckland City Hospital Oncology Services
Dr	Gunther Kothen	Training Manager & NZ Representative	Sirtex Medical Ltd
Assoc. Prof	Geoff Krissansen	Associate Professor	Molecular Medicine, University of Auckland
Dr	Euphemia Leung	Senior Research Fellow	Auckland Cancer Society Research Centre
Ms	Wing-Yee Lo	PhD Student	Molecular Medicine, University of Auckland
Ms	Daphne Mason	Curator	Middlemore Tissue Bank
Professor	John McCall	Transplant & Hepatobiliary Surgeon	Auckland City Hospital
Ms	Melissa Murray	Clinical Research Officer	Cancer Trials New Zealand
Ms	Kasturi Naicker	Secretary/Administrator	Cancer Trials New Zealand
Ms	Addah Nyawo	Contracts Manager	Auckland Uniservices Limited
Ms	Stephanie Pollard	Research Manager	Cancer Trials New Zealand
Ms	Janie Proctor	Clinical Research Officer	Cancer Trials New Zealand
Dr	Rekha Raju	Radiology Registrar	Middlemore Hospital
Dr	Stuart Ryan	Director	Centre for Clinical Research and Effective Practice
Ms	Jade Scott	Clinical Research Officer	Cancer Trials New Zealand
Dr	Katrina Sharples	Senior Biostatistician	Cancer Trials New Zealand
Ms	Viviana Zhang	Clinical Trial Coordinator	Auckland City Hospital Oncology Services